

Clinical Edit Criteria Proposal

Drug/Drug Class: Lyrica® Capsules Clinical Edit

Date: April 19, 2005

Prepared for:

Prepared by: Missouri Medicaid

☒ New Criteria

☐ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Lyrica® (pregabalin).

Why was this Issue Selected: Lyrica® is a branded drug product containing pregabalin. Pregabalin is a GABA analogue with structural similarity and actions similar to gabapentin. It has demonstrated efficacy for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and as adjunctive therapy for adults with partial onset seizures. Lyrica® is the first FDA approved treatment for both of these neuropathic pain states. Lyrica® has linear pharmacokinetics and has been designated as a Schedule V controlled substance. For patients who don't respond to gabapentin, Lyrica® may be a useful alternative.

Program-specific information:	Drug	Dosage	Monthly Cost**
	<ul style="list-style-type: none">• Lyrica®• Gabapentin	<i>50mg TID</i> <i>300mg TID</i>	<i>\$178.20 AWP</i> <i>\$119.66 AWP</i>

**Monthly cost for treatment of epilepsy, partial seizure in adults

Setting & Population: All patients.

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources: ☐ Only administrative databases

☒ Databases + Prescriber-supplied

Setting & Population

- Drug for review: Lyrica® (pregabalin)
- Age range: All ages
- Gender: Male and female

Approval Criteria

- Appropriate Diagnosis:
 - Therapy will be approved for the following indications:

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Peripheral Neuropathy assoc. with diabetes	250.6x 356.9x 357.2x	Yes
Postherpetic Neuralgia	053.12x 053.13x 357.0x	--
Partial Epilepsy	345.4x 345.5x	--

- Documented trial and failure on gabapentin.
- Documented ADE/ADR to gabapentin.
- Compliance on Lyrica therapy.

Denial Criteria

- Failure to meet approval criteria.

References

1. Facts and Comparisons, p.1006 – 1043c. 2005.
2. USPDI, Micromedex, 2005.
3. Pfizer, Inc., AMCP Formulary Submission Dossier - Lyrica®, Parsippany, NJ. 07054. August 2005.

